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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,041	12/03/2003	Samuel J. Danishefsky	2003080-0142 (SK-893-B-US	4230

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1643	
MAIL DATE	**DELIVERY MODE**
04/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,041	DANISHEFSKY ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) *48-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 5, 8, 14, 32-36 have been amended. Claims 1-58 are pending. Claims 48-58 remain withdrawn from consideration. Claims 1-47 are under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-7, 9-30, 32-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a multi-antigenic construct comprising carbohydrate domains, or elongated versions thereof that are present on tumor cells, does not reasonably provide enablement for a multi-antigenic construct comprising truncated versions of carbohydrate domains that are present on tumor cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims..

Claims 1 and 36 have been amended to recite "each occurrence of A independently comprises a carbohydrate domain, or truncated or elongated version thereof that is present on tumor cells.

The specification fails to provide teachings regarding a minimal structure within the disclosed carbohydrate domains which would function to elicit antibodies which would specifically bind to tumor cells within a patient. One of skill in the art would be forced to determine the minimal epitope as a "truncated version" of all of the carbohydrate tumor antigen that fall within the scope of that claims, wherein said "truncated version" would elicit antibodies that are capable of specifically binding with tumor cells within a patient. One of skill in the art would be subjected to undue experimentation in order to practice the broadly claimed methods requiring truncated version of a carbohydrate domain.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-44, 46 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Danishefsky et al (U.S. 7,160,856)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Danishefsky et al disclose glycoconjugate structures and the synthesis thereof which anticipate the instant constructs and compositions. Danishefsky et al disclose that the Rd, Re and Rf carbohydrate domains of the glycoconjugate are independently selected (for example, claim 3), and therefore encompass non-identical carbohydrate domains. Danishefsky et disclose conjugates in which it is specifically states that not all of Rd, Re and Rf are the same (claim 28)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 1, 3-6, 9-35, 37-47 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 56, 58-62, 65-67, 69-76, 78-81, 84-86, 88-98 of copending Application No. 09/641,742 is maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '742 application anticipate the constructs with a spacer, because the limitations claimed in claim 62 of the reference patent fulfill the instant limitations of claims 11 and 12 with regard to a spacer. Further claim 74 of the reference application also indicate that "t is 1-8" methylene groups which also fulfils the instant limitation of claims 11 and 12. Further, claim 74 of the reference application specifies that "n is 1-8" which fulfills the instant limitations for claims 5-7.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The provisional rejection of claims 1, 3-7, 9-22, 24, 31-33, 35, 37, 39, 40, 43-47 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 118-129, 132-137, 138-146, 148-168 of copending Application No. 10/209,618 is maintained for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '618 application anticipate the constructs with a spacer, because the limitations claimed in claim 128, 129, 140, 151 and 152 of the reference

patent fulfill the instant limitations of claims 11 and 12 with regard to a spacer and in particular, claim 140 includes "linear or branched chain alkyl". Further claims 132 and 133 of the reference application also indicate that "n is 0-9" and "n is 3"methylene groups which also fulfils the instant limitation of claims 5-7. Claims 154-159 of the reference patent are product by process claims and anticipate the instant invention through identity of the species in claim 118 of the reference application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-44, 46 and 47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 7,160,856. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '856 patent anticipate the instant claims to the extent that Rd, Re and Rf are not identical. The claims of the '856 patent compass both monoantigen structures and multi-antigenic structures (claim 28).

All other rejections and objections that are set forth or maintained in the previous Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/
Primary Examiner, Art Unit 1643